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No. 98-1768

IN THE
Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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June 2, 1999

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MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* SUPPORTING PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, Danek Medical, Inc. ("Danek") requests leave to file the accompanying brief as *amicus curiae* in support of the petition for writ of certiorari. Counsel for petitioner consented to the filing of this brief, but counsel for respondent declined.

Danek is the largest supplier of the spinal implant devices in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, from which this petition for certiorari arises. Danek brought the initial motion to dismiss claims of fraud committed against the Food and Drug Administration ("FDA"), *see* Petitioner's Appendix ("Pet. App.") at 33a-44a. Danek sought to participate in current appeal, but because other claims against it remained, the Court of Appeals held that Danek lacked standing. *See* Pet. App. at 8a n.3. Danek was permitted to participate as *amicus curiae* in the Court of Appeals. *Id.*

Danek should be permitted to participate as *amicus curiae* before this Court because, as a supplier of orthopedic bone screws, it is the target of the full range of the "fraud-on-the-FDA" claims raised in this litigation. Accordingly, Danek has relevant information concerning the broader impact of "fraud-on-the-FDA" claims, both in this litigation and upon FDA administrative determinations generally.

Thus, Danek's participation as *amicus curiae* will assist the Court in understanding the profound impact of allowing common-law reexamination of the basis of any FDA decision—and by extension, any federal administrative action—in private tort actions under state law.

For the foregoing reasons, Danek respectfully requests the Court to grant its motion for leave to file the accompanying brief as *amicus curiae* in support of the petition.

Respectfully submitted,

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Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994) 9

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In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (Pet. App. 1a-32a) 10,11,12,14

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In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, 1996 WL 482977 (E.D. Pa. Aug. 22, 1996) (PTO 477) 3,5

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Takhar v. Kessler, 76 F.3d 995 (9th Cir. 1996) 8

Talbott v. C.R. Bard, Inc., 63 F.3d 25, *cert. dismissed*, 517 U.S. 1230 (1996) 14

United States v. Ballistrea, 101 F.3d 827 (2d Cir. 1996) 8

TABLE OF AUTHORITIES—*(Continued)*

Cases: **Page(s)**

United States v. Bhutani, __ F.3d __, 1999 WL 25042 (7th Cir. Apr. 28, 1999) 8

United States v. C.R. Bard, Inc., 848 F. Supp. 287 (D. Mass. 1994) 8

United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995) 8

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21 C.F.R. §821.20 7

21 C.F.R. §820.25 7

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S. Rep. No. 33, 94th Cong., 2d Sess. (1976) (reprinted at 1976 U.S.C.C.A.N. 1070) 2

S. Rep. No. 284, 104th Cong., 2d Sess. (1996) 6

S. Rep. No. 468, 101st Cong., 2d Sess. (1990) 6

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63 Fed. Reg. 40025 (FDA Jul. 27, 1998) 3,4,5

TABLE OF AUTHORITIES—*(Continued)*

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FDA Disqualified/Restricted Assurances List for Clinical Investigators (last modified Apr. 29, 1999) <http://www.verity.fda.gov> 9

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Restatement (Second) of Torts §310 & comment c (1965) 10

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BRIEF OF DANEK MEDICAL, INC. AS *AMICUS CURIAE* SUPPORTING PETITIONER

INTEREST OF THE *AMICUS CURIAE*

The interest of Danek Medical, Inc. ("Danek") as *amicus curiae* is described in the preceding motion for leave to file this brief.[1]

SUMMARY OF ARGUMENT

Respondent Plaintiffs' Legal Committee ("PLC") represents hundreds of plaintiffs in personal injury litigation against suppliers of orthopaedic bone screws used in plaintiffs' spines during spinal fusion surgery. "Fraud on the FDA" is one of the PLC's many state-law claims. The PLC asserts that virtually every important FDA decision concerning these screws since 1986 rests upon untrue information provided by the suppliers of these devices or by their agents. This "fraud," the PLC claims, allows state-law juries to treat these FDA regula-

1. No counsel for any party authored any portion of this *amicus curiae* brief, and no one other than Danek made any monetary contribution to the preparation or submission of this brief. Supreme Court Rule 37.6.

tory actions as if they did not exist, and to hold Danek and other defendants liable for supplying products lacking any FDA marketing permission.

Either under the express preemption provision of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §360k(a), or under principles of implied preemption, this novel claim of "fraud on the FDA" is preempted. Otherwise, a jury in a state-law action could reexamine almost everything the FDA does, and different juries may reach different conclusions regarding the validity of FDA actions. The pervasive interference with FDA actions that "fraud-on-the-FDA" claims entail is exemplified by the breadth of the PLC's charges against Danek in this very litigation.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need for regulation of medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that balance—preservation of the FDA's ability to do its job without being second-guessed in state tort litigation—is directly presented to the Court by the certiorari petition filed by the Buckman Company.

2. *See* S. Rep. No. 33, at 7 (1976) ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven, ineffective and experimental medical devices" is "counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

I. "Fraud-on-the-FDA" Claims Expose FDA Decisions To Collateral Attack In State Courts, In Direct And Inherent Conflict With The Regulatory Scheme Enacted by Congress.

A. *The PLC's Claims Seek State Jury Nullification Of Every FDA Decision Regulating Spinal Implants Between 1986 and 1998.*

The PLC has brought "fraud-on-the-FDA" allegations against a wide range of FDA decisions involving every manufacturer of orthopaedic bone screws. *See* Petitioner's Appendix ("Pet. App.") at 43a-44a; *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1996 WL 482977, at *2 (E.D. Pa. Aug. 22, 1996) (PTO 477). These claims contest the validity of scores of FDA clearances of spinal implant devices since 1984, as well as the 1995 FDA decision to begin clearing "pedicle screws" as such and the general reclassification of "pedicle screw spinal systems" that the FDA proposed in 1995 and finalized in 1998. *See* 63 Fed. Reg. 40025 (FDA Jul. 27, 1998); 60 Fed. Reg. 51946 (FDA Oct. 4, 1995).[3]

The *John Lee Ramey* complaint, the MDL Court's exemplar of claims against Danek[4] (reproduced in pertinent part as Appendix "A") reveals the scope of the PLC's "fraud-on-the-FDA" claims. It alleges that the initial 1986 FDA clearance of the Danek "Luque II" components used in Mr. Ramey's surgery seven years later in 1993, was fraudulent because Danek supposedly misstated the "intended use" of the screw components. App. "A" at 3a ¶¶90-100. There is no claim that Mr. Ramey, his surgeon, or anyone involved in his treatment knew of or acted in detrimental reliance upon any misstatement. *Id.* at 8a ¶¶126-28.

The *Ramey* complaint further alleges that Danek defrauded the FDA with respect to devices not used in Mr.

3. The FDA's Final Rule was published on July 27, 1998, after oral argument in the Third Circuit. FDA decisions published in the Federal Register are entitled to judicial notice. 44 U.S.C. §1507.

4. *See In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1997 WL 186325, at *2 n.3 (E.D. Pa. Apr. 16, 1997) (PTO 861).

Ramey's surgery. These allegations likewise involve "intended use," rather than the physical characteristics, medical risks, or medical benefits of any device:

- In 1988-89, Danek allegedly misstated the "intended use" of "sacral" screw components of a device called the "TSRH" system. *Id.* at 6a-7a ¶¶105-110, 114-15.
- In 1990-92, Danek allegedly misstated the "intended use" of "variable angle" screw components of the TSRH system. *Id.* ¶¶111-15.
- In 1991-92, Danek allegedly misstated the "intended use" of the screw components of a device called the "Dyna-Lok" system. *Id.* at 7a-8a ¶¶120-25.

Further allegations of fraud involve the FDA's January 20, 1995 decision to clear TSRH screws specifically for use in the lumbar pedicles of the spine. Although this event occurred after Mr. Ramey's 1993 surgery, the PLC alleges that Danek (aided by other screw suppliers) submitted a false affidavit to prove that there was a pre-Amendments "substantially equivalent" device.[5] App. "A" at 13a-18a ¶¶244-75.

Still more fraud allegations in the *Ramey* complaint involve the FDA's October 4, 1995 proposal to reclassify "pedicle screw spinal systems" generally as safe and effective. The PLC attacks a large "cohort study" that the FDA concluded was "valid scientific evidence" of the safety and effectiveness of bone screws when used for pedicle fixation. *Id.* at 3a-13a ¶¶240-43. *See* 60 Fed. Reg. at 51947, 51950-54.[6]

The PLC's "fraud-on-the-FDA" allegations in this litigation thus are not limited to one device or one supplier. Rather, they attack the FDA's decision to allow marketing of most of the spinal fixation devices that now exist. Each action also seeks to void all the regulatory steps that the FDA has taken

5. The Danek clearances at issue all involve the same "substantial equivalence" procedure that was described by the Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-480 (1996).

6. Reclassification is a separate process by which a device can receive a lower device classification if the FDA is presented with "valid scientific evidence" of the device's safety and effectiveness. 21 U.S.C. §360c(e); 21 C.F.R. §§860.7, 860.120-860.134.

since 1995 to address the regulatory status of these devices. There are hundreds of these cases. *Orthopedic Bone Screw*, 1996 WL 482977, at *9. Each is nothing less than an attempt to use state law to nullify ten years of FDA regulatory activity.

The PLC persists even though the FDA examined the same fraud allegations and found them wanting. The FDA's proposal to reclassify spinal implants invited public comments, and the MDL Court allowed the PLC to use MDL discovery in its comments.[7] On March 1, 1996, the PLC filed several hundred pages of comments with the FDA—including the basis for its "fraud-on-the-FDA" claims against Danek.[8]

On July 27, 1998, as part of its Final Rule approving reclassification, the FDA addressed the PLC's fraud claims. It rejected the PLC's allegations that bone screws should be prohibited due to "deception":

> After reviewing all available data and information, . . . FDA does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury. Consequently, FDA does not believe it would be appropriate to ban them.

63 Fed. Reg. at 40035-36 (Item 28). The FDA further determined to retain all existing screw clearances. *Id.* at 40031 (Item 8), 40032-33 (Items 13-16), 40039 (Item 44). In reaching this decision, the FDA reviewed the PLC's fraud allegations involving the 1995 Danek TSRH clearance and the "cohort study" in great detail and rejected the PLC's claims point by point. *Id.* at 40032-33 (Items 13-16) (TSRH clearance); at 40029-30 (Items 2-3) ("cohort study").

7. *See* 60 Fed. Reg. at 51946 (setting public comment period); *In re Orthopedic Bone Screw Products Liability Litigation*, MDL-1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 14, 1995) (PLC may use confidential MDL documents in FDA public comments) (PTO 179).

8. *See* "Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket 1014, Concerning Proposed Rule Making," FDA Dkt. No. 95N-0176 (filed March 1, 1996).

The scope of the PLC's "fraud-on-the-FDA" allegations in the *Orthopedic Bone Screw* litigation, coupled with the FDA's adverse determination of them, point out the error of the Court of Appeals' reasoning. The PLC's attempt to overturn FDA clearances of every device involved in this litigation demonstrates that "fraud-on-the-FDA" claims do indeed seek to impose a legal requirement—not to sell the same devices that the FDA has cleared to be marketed—that is "different from or in addition to" FDA requirements imposed under the FDCA, *see* 21 U.S.C. §360k(a), and are therefore preempted.

Just as starkly, these claims illuminate how any "fraud-on-the-FDA" claim inherently conflicts with the specific FDA action that the claim seeks to nullify, and is therefore impliedly preempted. *See McDermott v. Wisconsin,* 228 U.S. 115, 132-34 (1913); *Lewis v. Brunswick Corp.,* 107 F.3d 1494, 1502 (11th Cir. 1997), *cert. dismissed,* 118 S. Ct. 1793 (1998). Because litigants in individual state-law cases may not ask lay juries to reexamine complex FDA decisions to allow medical devices and drugs to enter a nationwide market, this Court should grant the petition for certiorari.

B. *The Regulatory Structure Enacted By Congress Precludes The PLC's Attempted Collateral Attack Upon FDA Decisions.*

The vast potential of state-law "fraud-on-the-FDA" claims to disrupt FDA administration of the FDCA is also apparent from the FDA's role in the statutory scheme. The FDCA does not vest the FDA with authority to seek out and investigate drugs or medical devices for possible clearance. *Benton v. Kessler,* 799 F. Supp. 281, 284-85 (E.D.N.Y.), *mot. denied,* 506 U.S. 1084 (1992); *see* S. Rep. No. 468, at 204, 101st Cong., 2d Sess. (1990) (no FDA authority to establish clinical research facilities). Nor does the FDA have authority to evaluate off-label uses on its own volition. *See* S. Rep. No. 284, at 76, 104th Cong., 2d Sess. (1996). Like many administrative bodies, the FDA acts in response to information that the governing statute requires regulated persons, and allows others, to submit to the Agency.

FDCA requirements for submission of information to the FDA are pervasive. Each of the three avenues by which medical devices come onto the market requires evaluation of information submitted by manufacturers, distributors, and their agents.[9] The same is true with the processes for approval of new drugs and biologics.[10] After the FDA has given permission for a product to be marketed, manufacturers and distributors must provide a wide variety of additional information to the FDA, any of which could lead to future FDA action.[11] Every FDA action based upon submitted information is potentially subject to second-guessing and common-law nullification if "fraud-on-the-FDA" claims survive preemption.

Nor does the FDA need common-law assistance because it cannot defend itself from an onslaught of false information.

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9. *See* 21 U.S.C. §360e(c); 21 C.F.R. §814.20 (describing information to be submitted to the FDA in support of pre-market approval application); 21 U.S.C. §360c(e-f); 21 C.F.R. §860.123 (same; reclassification); 21 U.S.C. §§360(k), 360e(b); 21 C.F.R. §§807.87-807.93 (same; pre-market notification).

10. *See* 21 U.S.C. §355(a-d,i); 21 C.F.R. §§312.20-.23, 314.50-.54 (submission requirements for new drugs); 42 U.S.C. §262(a,j); 21 C.F.R. §§601.3, 601.20-601.25 (submission requirements for new biologics).

11. **Devices:** *E.g.,* 21 U.S.C. §§360i (record keeping), 360j(f)(2) (variance from good marketing practices), 360l (post-market surveillance); 360ll, 360nn(a-b,d,f) (electronics inspection/reporting), 360aaa-3 (supplemental application for new use); 21 C.F.R. §§803.1-.56, 804.1-.35 (adverse experience), 806.10, 820.100 (corrections), 807.20-.31 (device/establishment listing), 810.10(d), 810.15-.16 (cease distribution/recall), 820.30 (design/development), 820.70(b) (production/process changes), 820.120 (labeling), 820.181-.186, 821.50 (records), 820.198 (complaints), 821.20-.25 (device tracking), 860.7, 860.120-860.134 (reclassification). **Drugs:** *E.g., 21* U.S.C. §§355(k) (record keeping), 356b (postmarketing study), 356c (discontinuation), 360 (registration/listing), 360b(e)(1)(F) (failure to supplement application); 21 C.F.R. §§201.1-.15, 201.50-.57, 201.60-.63, 211.134(d,e), 314.70 (labeling), 207.20-.37 (establishment/drug listing), 211.180-.196 (record keeping), 211.198 (complaints), 310.303, 314.81, 314.420 (records/reports), 314.54 (indication changes), 314.70-.71 (supplement to approved application), 314.72 (change of ownership), 314.80 (adverse experience). **Biologics:** *E.g.,* 21 C.F.R. §§600.12 (record keeping), 600.14 (errors), 600.21-.22 (inspections), 600.80 (adverse experience), 600.81 (distribution), 601.4 (licenses), 601.12 (changes to approved applications), 601.26 (reclassification), 610.9, 610.11(c) (procedure modifications), 610.60-.64 (labeling).

Quite the contrary, the FDCA provides the FDA with an imposing arsenal of sanctions should it conclude that it has been the victim of fraud. In addition to felony criminal sanctions under 18 U.S.C. §1001, the FDA has numerous administrative sanctions at its disposal:

- injunctions against violations or further marketing, 21 U.S.C. §332;
- enhanced criminal penalties upon proof of "intent to defraud," *id.* §333(a);
- civil fines up to $1,000,000, *id.* §§333(b)(2)(B), 333(f)(1)(A), 335b(a);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- detention without prior notice, *id.* §334(g);
- barring implicated companies or individuals from involvement with further submissions to the FDA, *id.* §335a(a-e);
- denial, suspension, or termination of activities tainted by fraud, *id.* §335a(f-h);
- withdrawal of approval, *id.* §335c;
- warning letters for "minor violation[s]," *id.* §336;
- permanent ban of the product at issue, *id.* §360f; and
- mandatory recall. *Id.* §360h(e).

Nor has the FDA been reluctant to use its powers. Recent case law abounds with examples of prosecutions for making false statements to the FDA.[12] Many FDA enforcement actions are for false or fraudulent submissions. For example, from March 1993 through June 1998, the FDA permanently debarred 47 persons and temporarily debarred 2 others for

12. *E.g., United States v. Bhutani,* __ F.3d __ , 1999 WL 25042 (7th Cir. Apr. 28, 1999); *Takhar v. Kessler,* 76 F.3d 995 (9th Cir. 1996); *United States v. Ballistrea,* 101 F.3d 827 (2d Cir. 1996); *DiCola v. FDA,* 77 F.3d 504 (D.C. Cir. 1996); *United States v. Chatterji,* 46 F.3d 1336 (4th Cir. 1995); *United States v. Garfinkle,* 29 F.3d 1253 (8th Cir. 1994); *United States v. Radix Laboratories, Inc.,* 963 F.2d 1034 (7th Cir. 1992); *see also United States v. C.R. Bard, Inc.,* 848 F. Supp. 287 (D. Mass. 1994); *In re Grand Jury Proceedings,* 861 F. Supp. 386 (D. Md. 1994).

providing false information.[13] The FDA has also disqualified 87 clinical investigators from further participation in clinical trials and has restricted numerous others.[14]

In direct contrast to the FDA's multi-faceted enforcement capabilities, the FDCA provides no enforcement role for would-be "private attorneys general" such as the PLC. The FDCA specifically states:

> Except as provided in subsection (b) of this section [relating to actions by state governments], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a). On the strength of §337(a), this Court in *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 477 (1996), and every Court of Appeals to consider the question, has held that no private rights of action exist under the FDCA.[15]

Congress further manifested its intent that the FDA should control FDCA enforcement by granting prosecutorial discretion to the FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution. . .minor violations of this chapter whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning.

21 U.S.C. §336. "The Act's enforcement provisions. . .commit complete discretion to [FDA] to decide how and when they should be exercised." *Heckler v. Chaney,* 470 U.S. 821, 835

13. *See FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy—Debarment List* (last modified Sep. 28, 1998) <http://www.fda.gov/ora/compliance_ref/debar/default.htm>.

14. *See FDA Disqualified/Restricted Assurances List for Clinical Investigators* (last modified Apr. 29, 1999) <http://www.verity.fda.gov>.

15. *PDK Labs, Inc. v. Friedlander,* 103 F.3d 1105, 1113 (2d Cir. 1997); *Bailey v. Johnson,* 48 F.3d 965, 968 (6th Cir. 1995); *Mylan Laboratories, Inc. v. Matkari,* 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied,* 510 U.S. 1197 (1994); *Rodriguez v. SK&F Co.,* 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark,* 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.,* 547 F.2d 367, 370 (7th Cir. 1976).

(1985). As discussed, *supra,* at pp. 4-5, the FDA spent more than two years investigating the PLC's "fraud-on-the-FDA" claims before rejecting them in issuing its 1998 Final Rule.

Ad hoc reexamination of FDA decisions by lay juries in state-law actions around the country is incompatible with the regulatory structure Congress has put in place. The PLC seeks to "use the threat of damages to require [defendants] to do exactly what [the FDA] is empowered to excuse." *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.,* 450 U.S. 311, 326 (1981). The PLC wants state-law juries to disagree with the FDA's 1998 rejection of its fraud allegations. The FDCA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission,* 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption maintains both the FDA's exclusive enforcement powers and its prosecutorial discretion.

II. Contrary To The Third Circuit, This Court Did Not Hold In Medtronic That "Fraud-on-the-FDA" Claims Were Not Preempted.

The Third Circuit did not profess to recognize a private FDCA action for "fraud on the FDA." *See* Pet. App. at 13a. Rather, without citation, the Court of Appeals held, "[w]e see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and private plaintiffs "bring[ing] common-law fraudulent misrepresentation claims." *Id.* at 18a. The error in this reasoning is that "fraud on the FDA" is not a traditional common-law fraud claim, but instead is fundamentally different.

Traditional fraud claims are predicated upon a defendant, directly or indirectly, passing false information to a plaintiff, who detrimentally relies upon that information.[16] The PLC

16. *See* Restatement (Third) of Torts, Products Liability §9 & comment c (1997) (misrepresentation must be "in connection with the sale of a product," and reliance is required); Restatement (Second) of Torts §402B & comment j (1965) (misrepresentation must be "to the public," and reliance is required); Restatement (Second) of Torts §310 & comment c (1965) (must be reliance upon the misrepresentation, such as a third person's mistaken belief as to safety); Restatement (Second) of Torts §§537, 548 (1976) (must be reliance upon the misrepresentation).

does not claim that any plaintiff, treating surgeon, or anyone outside the FDA[17] relied upon, knew of, or even had reason to know of, allegedly false statements of "intended use" made to the FDA years before their surgeries.

Nor are tort actions based upon procedural irregularities. "Negligence *per se*" involves violation of substantive safety standards.[18] Administrative guidelines, such as the content of administrative submissions, do not give rise to tort claims for their violation.[19] Procedural attacks upon federal administrative decisions are federal questions governed by the Administrative Procedure Act ("APA").[20] "Fraud on the FDA" is not a "field which the States have traditionally occupied." *Medtronic,* 518 U.S. at 485 (citation and quotation marks omitted).

The PLC's "fraud-on-the-FDA" claims are dependent, not upon traditional tort reliance, but rather upon the claimed invalidity of FDA actions. The Third Circuit recognized this fact, but failed to appreciate its significance. *See* Pet. App. at 21a ("without Buckman's fraudulent representation, the FDA would not have given AcroMed a §510(k) clearance and that, absent a §510(k) clearance, AcroMed would not have access to the market"). Thus, the PLC's "fraud-on-the-FDA" claims

17. Federal law exempts FDA employees from civil discovery regarding their performance of FDA duties. 21 C.F.R. §20.1(a-b). Thus the most crucial evidence of the actual effect of supposed "fraud" upon internal FDA decision-making is unavailable to civil litigants.

18. *See* Restatement (Third) of Torts, Products Liability §4, comment a (1997) (violation claims limited to "final governmental edicts and directives . . . that establish binding safety standards").

19. *See* Restatement (Second) of Torts §288(a) (1965) (negligence *per se* not applicable to enactments that "protect the interests of the state or any subdivision of it as such").

20. *See, e.g.,* 5 U.S.C. §702; 28 U.S.C. §1331. Indeed, the PLC is simultaneously prosecuting an APA action against the 1998 FDA Final Rule. *See Cosom, et al. v. United States Food & Drug Administration,* C.A. No. 98-CIV-4643 (E.D. Pa.).

empower common-law juries to nullify administrative actions taken by the FDA—by declaring the "absence" of those FDA actions.

The PLC does not seek repetition of any FDA proceeding with "truthful" information. Rather, it wants juries to void FDA actions retroactively and to award damages. The conflict between this "tort" and a specific FDA requirement (here, clearance for marketing) imposed upon a specific device is total, because a jury is to be asked to treat a standing FDA decision as invalid. The conflict is also inherent, because unless the jury nullifies the FDA decision, the PLC's claim cannot succeed.

Nor was the Third Circuit correct to rely upon the rationale of the *Medtronic* plurality that lack of private FDCA rights of action was "evidence of an intent *not* to preempt common law liability." Pet. App. at 15a (citing *Medtronic*, 518 U.S. at 487) (emphasis original). *Medtronic* did not involve any claim having nullification of an FDA action as an essential element. The *Medtronic* plurality rejected an argument that §360k(a) preempted all state-law claims—a discussion that is inapposite, since the PLC may pursue (and is pursuing) unpreempted claims such as design and warning defects. No member of this Court held in *Medtronic* that, no matter how great the conflict with the FDA's interpretation of its requirements, no state-law claim could be preempted.

"Fraud on the FDA" is not analogous to any claim at issue in *Medtronic*, and the Court of Appeals' decision would avoid even preemption that is appropriate under *Medtronic*. No member of this Court disagreed with Justice Breyer that "a federal MDA regulation requir[ing] a 2-inch wire" would preempt a state tort claim "that use of a more than 1-inch wire is negligent." 518 U.S. at 504 (Breyer, J., concurring). But the Third Circuit would require only a claim that the "2-inch" regulation was the product of fraud upon the FDA to avoid preemption.

In particular, "fraud on the FDA" is the polar opposite of the "identity of requirements" claim that *Medtronic* unanimously held was not preempted.[21] In *Medtronic* the only allegation was that the defendant "violated FDA regulations." 518 U.S. at 495. The state-law duties in *Medtronic* thus "paralleI[ed] federal requirements." *Id.* Here, "fraud on the FDA" requires state-law juries to set aside what the PLC claims are fraudulently obtained FDA clearances—despite those fraud allegations having been investigated by the FDA and determined to be without merit. A greater divergence between the requirements of federal and state law would be difficult to envision.[22]

Danek is a national seller of medical devices, and the *Orthopedic Bone Screw* litigation is equally nationwide in scope. After the Court of Appeals' decision, however, Danek faces the likelihood that the validity *vel non* of the FDA clearances for its devices—and thus Danek's ability to market its products at all—may vary from state to state, or even within a state, depending on conflicting verdicts of lay juries.

"Fraud-on-the-FDA" claims also have practical ramifications. *First*, while the FDA only requires submission of one "intended use" to support device clearance, *see* 21 C.F.R. §807.92(a)(5), the PLC's claim effectively demands FDA submission of full information about every possible "intended use"—forcing the FDA to wade through information that the Agency neither wants nor needs.

Second, suppliers of medical devices and drugs could not inform physicians of medical advances using their products, as permitted by the FDCA, 21 U.S.C. §360aaa, without fear of exposing their FDA-recognized "intended uses" to state-law challenge as "fraudulent."

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21. 518 U.S. at 494–97 (opinion of the Court), 513 (O'Connor, J. concurring, joined by the Chief Justice and Scalia and Thomas, JJ.)).

22. The PLC's feigned allegiance to FDCA procedures cannot support its attempt to overturn the substantive FDA decisions resulting from those procedures. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation and quotation marks omitted).

Third, because fraud, rather than a defective product, is the basis of the claim, "fraud on the FDA" could be asserted by competing device and drug companies to interfere with their competitors' products. *Cf. Medtronic,* 518 U.S. at 494 & n.14 (discussing "procompetition" purpose of the FDA clearance process at issue in this litigation).

Collateral attacks upon FDA decisions threaten suppliers of medical devices and drugs with liability, not for defective products, but for marketing their products in reliance upon FDA decisions that any state-law jury may later decide should be retroactively annulled. This potential for divergent results is only aggravated by the conspicuous split among the circuits that the decision here opened.[23] Because subjecting medical device and drug manufacturers to inconsistent state-law decisions on the basic issue of whether their products are legally marketed was not what Congress intended when it enacted the FDCA, this Court should grant the petition for certiorari.

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23. *See* Pet. App. at 17a n.5 (acknowledging disagreement with *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998)). Other Court of Appeals decisions finding claims of fraud on an administrative agency preempted include: *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1839 (1998); *Lewis,* 107 F.3d at 1502; *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28 (1st Cir. 1995), *cert. dismissed,* 517 U.S. 1230 (1996); *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 306 (5th Cir.), *cert. denied,* 515 U.S. 1104 (1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993).

CONCLUSION

Because of the profound impact of allowing "fraud-on-the-FDA" claims, not only upon FDA administration and enforcement of the FDCA, but also upon the integrity of federal administrative actions generally, the Court should grant the petition for writ of certiorari.

Respectfully submitted,

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Dated: June 2, 1999

**Member of the Supreme Court Bar*

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

John Lee Ramey and Candice Ramey, Plainfiffs, v. Danek Medical, Inc.; Sofamor-Danek Group, Inc.; Warsaw Orthopedic, Inc.; Eduardo Luque; Charles E. Johnston, II; Richard Ashman, Ph.D.; Gary Lowery; George Rapp; Ensor Transfeldt; John A. Herring; Thomas Whitecloud, III; Thomas A. Zdeblick; Youngwood Medical Specialties, Inc., f/k/a/ National Medical Specialty, Inc., f/k/a/ Stuart Medical Specialty, Inc.; Stuart Medical, Inc., f/k/a/ Stuart Drug and Surgical Supply, Inc.; Texas Scottish Rite Hospital for Crippled Children; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; Spinal Science Advancement Foundation; Acromed Corporation, Charter No. 614043; Acromed Corp. (Now Acromed Corporation, Charter No. 614043); Acromed Corporation, Charter No. 816942; Acromed, Inc., Charter No. 811415; Acromed Incorporated (Now Acromed Inc., Charter No. 811415); Acromed Incorporated, Charter No. 816943; Acromed Holding Corporation, Charter No. 811416; Acromed Corporation (Now Acromed Holding Corporation, Charter No. 811416); Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; DePuy-Motech, Inc.; Smith & Nephew Richards, Inc.; Sofamor, S.N.C.; Sofamor, Inc.; Synthes (U. S.A.); Synthes, Inc.; Synthes North America, Inc.; Synthes; A.G.; Zimmer, Inc., Defendants.	MDL 1014 CIV. NO. 96-422 D. MD. CIV. NO. 95 CV 3194 JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

* * *

3. On March 1, 1993, Dr. A.H. Dudley performed surgery on Plaintiff at Children's Hospital in Baltimore, Maryland and implanted a Danek pedicle screw fixation device known as the Luque device in Plaintiffs spine.

* * *

Count I: Fraud (on the FDA)

* * *

84. Plaintiff repeats and realleges each and every allegation set forth in the paragraphs above and further alleges the following.

85. The claims made in Count I of this Complaint are made against Danek and Sofamor-Danek.

86. The Luque II plate and screw device was developed by Eduardo Luque ("Luque") specifically for use in spinal surgery involving the lower back. The device consists of plates and screws which are intended to be attached to the lumbar spine with screws inserted posteriorly through the lumbar pedicles in order to provide a means of internal stabilization in connection with spinal fusion surgery.

87. On March 26, 1986, Warsaw Orthopedic submitted a 510(k) notification to the FDA for the Luque II device which was described as the "Interpeduncular Segmental Fixation System."

88. Less than two months later, on May 6, 1986, the FDA determined that the device was a Class III device which was not substantially equivalent to any pre-enactment device and which, therefore, could not be sold in the United States without a premarket approval based data developed in prospective clinical trials pursuant to an approved IDE. In explaining this decision, the agency stated that the decision was based on the fact that there had not been adequate demonstration that there was a pre-amendment device with a design substantially equivalent to The Luque System and on the fact that it posed potential risks not exhibited by other spinal fixation systems, such as:

"1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;

2. pedicle fracture during placement of the screw;

3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and

4. greater risk of pseudoarthrosis due to instability of design."

89. Determined to immediately sell the Luque II device for spinal fixation, Danek conceived and implemented an unlawful and deceptive scheme to bring the Luque II device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

90. The unlawful plan contemplated that:

(a) Danek would fraudulently seek 510(k) clearance of the components of the Luque II system as "bone plates" and "bone screws" for use in repairing fractures of the long bones even though the sole intended use of the Luque II system was in spinal applications;

(b) Once clearance from the FDA was obtained, Danek would contend that the FDA determination of substantial equivalence constituted official notification from the FDA that the devices were safe and effective and that such devices could be introduced for commercial use; and

(c) Consistent with Danek's goal to sell the Luque II device in interstate commerce for its intended use as a pedicle screw fixation device, Danek would promote the device by using physicians such as Luque to train other physicians in spinal applications of the Luque II device.

91. Using this approach, on June 5, 1986 Danek submitted a 510(k) notification for the same device components which made up the ISF system for which 510(k) clearance had previously been denied.

92. In the June 5, 1986 submission, the system components were described as "the Warsaw Orthopedic Bone Plate and Cancellous Bone Screw."

93. The notification claimed that "[t]he screws are designed for use in all fractures treated with two or more cancellous lag screws, such as intracapsular fractures of the hip and femoral condyle and tibia plateau fractures."

94. With respect to the plate components, the notification stated that "[s]pecific application is of course within the purview of the physician, but the use of the device in conditions such as long bone osteotomy, pelvic fracture and arthrodesis of the knee and/or ankle is obvious."

95. Subsequent correspondence with the FDA on behalf of Danek in connection with the notification emphasized that the device was intended for general orthopedic use in the long bones and not for pedicle fixation.

96. A July 2, 1986 letter written on behalf of Danek to the FDA in connection with the notification falsely stated that the Warsaw screws were "intended for use in the treatment and management of orthopedic injuries or conditions that in the view of the physician will benefit from the application of metallic screws or metallic plates and screws. Generally, this means for the repair of osseous fractures or conditions using screws having enhanced holding power in the cancellous bone."

97. Further misrepresentations appear in an August 1, 1986 letter written on behalf of Danek to the FDA regarding use of the cancellous bone screws, in which it was stated that "[t]he manufacturer intends that the screw will be used to treat fractures of cancellous bone."

98. In reasonable and justifiable reliance on the misrepresentations made regarding the intended use of the plates and screws which were the subject of the June 5, 1986 510(k) notifications, the FDA cleared these components as substantially equivalent to pre-amendment devices.

99. The representations made by Danek in obtaining these 510(k) clearances were intentionally false and

misleading. L.D. Beard, who at the time was the President and Chief Executive Officer of Danek, conceded at a deposition that the intended use of the bone plates and bone screws which were the subject of the June 5, 1986 510(k) notifications was not for repair of fractures of the long or flat bones as set forth in those 510(k) notifications. Rather, he admitted that the sole intended use of the system and system components was for use in spinal applications (i.e., pedicle screw fixation) and that the only reason why the FDA was told otherwise was so that clearance could be obtained so that the device could enter the market where Danek intended to promote and sell it only as a pedicle screw/spinal plate fixation system.

100. At the time the FDA made its substantial equivalence determination with regard to the Luque II device (which was presented to the FDA as "Warsaw Orthopedic Bone Plates and Cancellous Bone Screws"), it was ignorant of the fact that Danek had misrepresented the intended use of the Luque II Plates and Screws and that the sole intended use of the device components was as pedicle screws and spinal plates assembled as a spinal fixation system.

101. On June 27, 1986, an application was submitted for Danek to conduct clinical trials of the Luque Intrapeduncular Segmental Fixation System pursuant to the Investigational Device Exemption provisions of the Food, Drug and Cosmetic Act. The stated purpose of the IDE application was to develop data on the safety and effectiveness of the Luque II device for pedicular fixation.

102. The FDA granted approval to conduct the IDE trials involving a limited number of physicians and institutions.

103. However, the Luque II IDE failed to generate sufficient information on safety and efficacy to permit the FDA to grant premarket approval of the device for its intended use as a pedicle screw fixation device.

104. Nevertheless, Danek marketed and promoted the Luque II device on a massive basis outside of the IDE trial solely for its intended use as a pedicle screw fixation device.

105. Danek also manufactures, markets, distributes and sells the Texas Scottish Rite Hospital ("TSRH") spinal system. This instrumentation system was developed by Richard Ashman, Ph.D., ("Ashman"), John Herring, M.D. ("Herring") and Charles Johnston, M.D. ("Johnston") at the Texas Scottish Rite Hospital in Dallas, Texas.

106. The TSRH system employs a pair of rods arranged along the vertical axis of the spine which are connected to the vertebrae with hooks, screws or both.

107. Danek did not seek clearance from the FDA to market the screw components of the TSRH system for use in the pedicles of the lumbar vertebrae which, anatomically, lie above the bony base of the spine known as the sacrum.

108. However, it did seek 510(k) clearance for sacral application of the TSRH screws.

109. On September 2, 1988 a 510(k) notification was submitted to the FDA for what was described as TSRH "sacral screws."

110. Based on the representation that these screws were intended to be used in the sacrum, the FDA determined, on April 6, 1989, that the TSRH sacral screws were substantially equivalent to pre-enactment device components.

111. On September 12, 1990, Danek submitted a 510(k) notification to the FDA for the TSRH Variable Angle Sacral Screw.

112. The notification stated that the Variable Angle Sacral Screw was a modification of the TSRH sacral screw and followed the same intended use.

113. Based on the representation that these screws were to be used in the sacrum, the FDA determined on January 22, 1992 that TSRH Variable Angle Sacral Screw was substantially equivalent to a pre-amendment device.

114. The representations made in the 510(k) notifications to the FDA concerning the intended use of TSRH sacral and variable angle sacral screws were intentionally false and misleading.

115. At the time Danek submitted these 510(k) notifications, Danek intended that the screws which were labeled as "sacral screws" would be used by surgeons in the pedicles of the lumbar spine. Indeed, Danek funded a book which was authored by the developers of the system concerning its use. The book was specifically written to go along with the system as part of the system itself. It was to serve as a "cornerstone" for courses and workshops concerning the use of the system and "as a way to stimulate users' interest in purchasing and employing the instrumentation." One Chapter of this book, Chapter 5, is dedicated exclusively to a discussion involving the use of TSRH "sacral screws" in the pedicles of the lumbar spine in order to create a fixation construct for treatment of degenerative spinal instability. The text and illustrations in this regard are unmistakable. Chapters 4, 6 & 7 of the book also describe the use of TSRH screws in the lumbar pedicles. These chapters together account for over half of the book.

116. Consistent with this, Danek expressly viewed the TSRH system as a "pedicle screw fixation system."

117. Danek did request and receive approval to conduct IDE clinical trials involving 10 institutions and 240 subjects in order to obtain clinical data on the safety and efficacy of pedicle screw fixation with the TSRH system.

118. The TSRH pedicle screw IDE did not develop sufficient data to result in a successful application for premarket approval.

119. Nevertheless, Danek marketed and promoted the TSRH device on a massive basis outside of its IDE trial for its intended use as a pedicle screw fixation device.

120. Danek also manufactures, distributes and sells the so-called "Dyna-Lok" Spinal Fixation System. The system is a plate and screw device.

121. On September 7, 1991 Danek submitted at [sic] 510(k) notification for the Dyna-Lok Fixation System. The application falsely stated that the device was substantially equivalent to the Warsaw Bone Plate, now called the Danek

Plate, and that the bone screws used in the Dyna-Lok device were substantially equivalent to the TSRH Sacral Screw.

122. In reliance on Danek's representations concerning the intended use of the Dyna-Lok device, on December 17, 1992, the FDA determined that the device was substantially equivalent to pre-amendment devices.

123. Danek's 510(k) notification for the Dyna-Lok Fixation System misrepresented the intended use of the device. The device was designed and intended exclusively for use as a pedicle screw fixation device.

124. All of the misrepresentations made by Danek to the FDA as set forth in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the Luque II, TSRH, and Dyna-Lok devices and device components in order to provide Danek with a pretext to claim that the devices could be lawfully introduced into interstate commerce.

125. The FDA was ignorant of the fact that these devices and device components were intended by Danek for use as pedicle screw fixation devices.

126. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for Danek's pedicle screw fixation devices and device components for any purposes, the devices would not have been introduced into interstate commerce, and the Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff.

127. The FDA, Plaintiff and Plaintiffs' implanting physicians relied upon Danek to make truthful statements to the FDA in its 510(k) notifications regarding the intended use of the devices at issue so that Plaintiff would not be implanted with a dangerous medical device that was never proven to be safe and effective for the use for which it was intended, i.e., pedicle screw fixation.

128. As a direct and proximate result of Danek's misrepresentations as set forth in Count I of this Complaint, Plaintiff suffered severe and permanent physical harm

including injuries to his spine, spinal nerves, spinal nerve roots and surrounding tissues, cells, nerves and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of damage, loss and harm.

* * *

B. The Intercompany/Association Conspiracy

* * *

238. By 1992, the manufacturers and sellers who marketed pedicle screw fixation devices in violation of federal law and the physicians and professional associations they conspired and acted in concert with expressed a need to find a means to avoid criminal prosecution and civil liability in connection with their past unlawful promotion of pedicle screw fixation devices and to legitimize the sale of such devices in the future.

239. In furtherance of the original goals of the intercompany/association conspiracy and as a means to avoid liability for past wrongful acts, those who participated in the intercompany/association conspiracy adopted and implemented a two-part scheme.

240. First, all of the members of the intercompany/association conspiracy agreed to the creation, funding, and support of a trade association which was named the Spinal Implant Manufacturers Group ("SIMG"), and a "Scientific Committee" to conduct a "Cohort Study" of pedicle screw fixation in a fraudulent and misleading manner and to use the "results" of this deceptive and misleading study:

(a) to achieve reclassification of pedicle screw fixation devices so that they could be legally marketed without the successful completion of prospective clinical trials and/or premarket approval;

(b) to avoid criminal prosecution for illegal sales and distribution of pedicle screw fixation devices; and

(c) to provide "scientific" evidence for use as part of a defense to litigation in which patients claimed that they suffered harm as a result of the use of pedicle screw fixation devices.

241. Pursuant to this scheme, data regarding the outcome of patients treated for spinal fracture and degenerative spondylolisthesis was gathered by SIMG, the Scientific Committee, AAOS, AANS, SRS, and NASS from spine surgeons who were selected to participate in the study; the data were received and analyzed by Biometric Research Institute, Inc. ("BRI"); and the results of the study were reported to an FDA advisory panel on July 22, 1994 and in a special issue of *Spine* magazine which was published on October 15, 1994.

242. Pursuant to the plan adopted by the members of the intercompany/association conspiracy, the manner in which the Cohort Study was conducted and reported was intentionally deceptive and materially misleading in that, among other things:

(a) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, the professional societies which designated representatives to serve on the Scientific Committee which was responsible for conducting the study (AANS, AAOS, SRS, and NASS), had significant financial relationships with the manufacturers and sellers of the pedicle fixation devices that were the subject of the Cohort Study which were not disclosed when the results of the study were reported;

(b) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, each of the members of the Scientific Committee which claimed responsibility for conducting the Cohort Study had a significant financial relationship with manufacturers of pedicle screw fixation devices, which became substantially

more generous on completion of the study. This circumstance was concealed from those to whom the study was reported.

(c) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, Hansen Yuan, M.D., who was chairman of the Scientific Committee which claimed responsibility for conducting the study was negotiating with two major pedicle screw manufacturers to license a new pedicle screw fixation device while the study was proceeding. Those manufacturers had made offers to pay him as much as one million dollars in cash and a percentage royalty worth as much as twenty-five million dollars for the license, making it explicit that the amount which Dr. Yuan would realize under these proposed arrangements was directly dependent on whether the FDA reclassified pedicle screw fixation devices as a result of the Cohort Study. Dr. Yuan concealed these transactions when the results of the Cohort Study were reported. Moreover, when Dr. Yuan was questioned concerning these transactions at a deposition and at a hearing, he falsely stated that he did not engage in these negotiations until the Cohort Study had been completed and gave false and misleading information concerning the agreement which he ultimately entered into for the licensing of the pedicle screw fixation system.

(d) In presenting the results of the Cohort Study to the FDA's advisory panel, the Scientific Committee represented that a sample of the Cohort study data was "assessed by an independent auditor pursuant to a plan which was based on a blinded, random site selection process" which demonstrated that the submitted data were accurate when, in fact, the only "audit" which was done was a revisit of five sites by a masters-level employee of Dr. Yuan, who later

admitted significant inaccuracies in data reporting and other material failures to comply with the study protocol.

(e) SIMG and the Scientific Committee adopted and implemented a policy to destroy virtually all documents related to the Cohort Study before the study was reported to the FDA advisory panel in violation of an existing document preservation order entered by a federal court and with the intent to destroy evidence concerning the manner in which the Cohort Study was created and implemented;

(f) BRI, which received and analyzed the Cohort Study data was directed by Order of the United States District Court for the Eastern District of Pennsylvania to produce all computer diskettes and documents in its possession concerning the study. Not only did BRI fail to comply with that order but it also falsely stated, under oath, that the computer diskettes in its possession concerning the study had technical defects which prevented it from making usable copies, that its computer backup system containing Cohort Study data had mysteriously "crashed," destroying the information encoded therein, and that it had virtually no documents in its possession concerning this study. After a lengthy hearing, however, it was "discovered" that BRI had usable computer diskettes which could be copied, that there was no "crash" of the BRI computer backup system and that BRI had boxes full of documents which were properly subject to production;

(g) In presenting the results of the Cohort Study, it was represented that the Cohort Study was "conducted" by the Scientific Committee and that the study data was collected or analyzed by the Scientific Committee when, in fact, the Scientific Committee was not familiar with the manner in which the study data was processed, the way in which it was verified, or the procedures which were developed and applied with regard

to missing, incomplete, and inconsistent data and did not perform or understand the statistical treatment of the Cohort Study data;

(h) The Cohort Study was purportedly designed to demonstrate the difference between the outcome of patients treated with pedicle screw fixation and the outcome of patients who were treated for the same conditions by other methods. However, the study intentionally distorted that comparison by excluding data from physicians who infrequently used pedicle screw fixation and frequently used other methods to treat the conditions under consideration;

(i) The physicians who participated in the study inaccurately reported the post-operative conditions of patients who underwent pedicle screw fixation surgery, selectively excluded data for patients who should have been included in this study and selectively included the data from patients who should have been excluded from the study;

(j) The study exacerbated the potential for reporting and selection bias by providing that data be submitted anonymously by spine surgeons; and

(k) In reporting the results of the study the fusion outcome in patients who received pedicle screw fixation surgery was falsely inflated in relation to the fusion rate achieved in patients who underwent fusion surgery without pedicle screw fixation.

243. To this date, Defendants involved in the Danek and intercompany/association conspiracies are attempting to use this fraudulent and misleading Cohort Study as a means of escaping liability in this and related litigation.

244. Beginning in the Spring of 1993, as the second aspect of the effort to achieve the legal marketing status for pedicle screw fixation devices through fraudulent and deceptive means, Danek and other manufacturers and sellers of pedicle screw fixation devices engaged in a collaborative industry-physician effort to deceive the FDA with respect to

the commercial use of a Harrington lag screw for pedicle fixation prior to 1976 in order to persuade the FDA that pedicle screws were substantially equivalent to pre-enactment devices and therefore deserving of 510(k) clearance without analysis of safety or efficacy.

245. Specifically, in furtherance of the goals of the intercompany/association conspiracy, AcroMed, Danek, Sofamor and Zimmer agreed to obtain fraudulent and false documents and testimony purporting to prove that Zimmer had made and sold a commercially available pedicle screw in the United States prior to May 28, 1976 and submit such documents and testimony to the FDA to secure 510(k) approval for the Danek TSRH system.

246. AcroMed, Danek, Sofamor and Zimmer knew that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

247. In fact, Zimmer's Director of Regulatory Affairs knew as early as November 1987 that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

248. Zimmer knew on or before May 20, 1992 that other manufacturers were "pursuing reclassification to pre-enactment status based upon some old Zimmer drawings found in a surgeon's files."

249. Rick Treharne of Danek called Michael Mayock of Sofamor, who was a former Zimmer employee, and requested that Mayock prepare an affidavit to be submitted with the Danek TSRH 510(k) application claiming falsely that Mayock had personal knowledge of a pre-enactment sale in the United States of a Zimmer pedicle screw.

250. Treharne and Mayock drafted numerous revisions of a proposed affidavit until Treharne composed and sent Mayock a document described by Treharne as the "perfect affidavit," which Mayock executed.

251. Mayock obtained approval from Sofamor before executing this "perfect" affidavit and another affidavit and then transmitted the same to Sofamor.

252. Mayock claimed in his affidavit that Zimmer made a pedicle screw product prior to May 28, 1976 that would meet the prerequisites of 510(k) approval, asserting falsely that Zimmer shipped a pedicle screw made by Zimmer in the United States to Zimmer distributor Keith Bartow, who then sold the screw to a Mexican doctor named Luque.

253. Keith Bartow did not sell pedicle screws made by Zimmer in the United States to Dr. Luque prior to May 28, 1976.

254. In fact, Keith Bartow did not even meet Dr. Luque until the early 1980's.

255. Danek Chief Executive Officer Beard called Zimmer President Ron Davis and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

256. Zimmer President Ron Davis instructed Zimmer General Counsel Timothy Wendt to conduct such research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

257. AcroMed Director of Regulatory Affairs Christianson also called Zimmer General Counsel Timothy Wendt and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

258. In addition, Danek employee Bailey Lipscomb or Danek employee Rick Treharne called Zimmer's Director of Regulatory Affairs Max Sherman and requested that Zimmer conduct research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

259. Sherman has testified that Zimmer had a policy against giving assistance to other manufacturers by providing them with supporting documents for 510(k) applications.

260. Nevertheless, Wendt ordered Zimmer employees to perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

261. Zimmer did not charge Danek for its research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

262. For pre-amendment status, FDA Compliance Policy Guide 7124.19 requires the following: (1) at least one United States sale pre-May 28, 1976 of a product made in the United States; (2) catalogue advertising; and (3) no research support. To prove the first point, the FDA requires either invoices or an affidavit explaining their absence.

263. Wendt executed two affidavits to be submitted to the FDA to assist in Danek's TSRH 510(k) application, explaining the absence of invoices purportedly proving at least one United States sale of a Zimmer pedicle screw pre-May 28, 1976.

264. Zimmer employee Gary Tanner prepared an affidavit to be executed by former Zimmer employee Ralph Welling that repeatedly used the term "pedicle screw" in reference to purported pre-May 28, 1976 screw usage by Zimmer, even though Welling had never before used the term "pedicle screw" or even heard such term before seeing his proposed affidavit.

265. Tanner prepared an affidavit to be executed by Ralph Welling that referenced purported pre-May 28, 1976 "pedicle screws" shipments and usage even though Welling had no personal knowledge whatsoever regarding whether or not the referenced screws were actually manufactured, sold or used.

266. The affidavits by Mayock, Wendt and Welling were essential to convince the FDA to approve the Danek TSRH 510(k) on the basis that they purportedly established that there was a United States pre-May 28, 1976 sale of a Zimmer "pedicle screw."

267. AcroMed, Danek, Zimmer and Sofamor knew that the factual claim in the Danek TSRH 510(k) filing that Zimmer made and sold a commercial pedicle screw in the United States that was not involved in research prior to May 1976 was false.

268. Indeed, Zimmer filed a "Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims And Zimmer, Inc.'s Brief In Support Of Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims" (hereinafter "Supplemental MSJ") on or about March 15, 1996 in MDL 1014, providing in pertinent part that:

(a) "Zimmer has never marketed any device which includes a screw intended for use in the lumbar pedicles" (p. 5);

(b) "Zimmer has never marketed a pedicle screw fixation system for use in the United States" (p. 10);

(c) "Zimmer does not now and has never marketed a spinal device which includes a screw intended for use in the lumbar pedicles of the spine" (p. 11);

(d) "Zimmer did not even have a product in the pedicle screw market" (p. 16);

(e) "The undisputed fact is that Zimmer did not have a product to sell in that market [pedicle screws]" (p. 17);

(f) "Zimmer never marketed a device that included a screw intended for use in the lumbar pedicles" (p. 18); and

(g) "Zimmer does not market a pedicle screw device" (p. 25).

269. Neither AcroMed, Danek, Sofamor nor Zimmer advised the FDA, and the FDA did not know, that Zimmer asserted that it "never marketed a pedicle screw fixation system for use in the United States," in direct conflict with the position set forth in the Danek TSRH 510(k) application.

270. Danek's Lipscomb and AcroMed's Christianson flew to Kansas together and collaborated on additional research for the Danek TSRH 510(k) application.

271. Sofamor employee Mayock testified that the joint research effort by AcroMed, Danek, Sofamor and Zimmer was "like a loose confederation."

272. Zimmer's Max Sherman stated in a July 14, 1989 memorandum that 510(k) approval for portions of Zimmer's

spinal implant system "would be a good defense item for litigation. (It would indicate Zimmer developed PSI using proper approval procedures.)"

273. AcroMed stated in a May 15, 1995 News Release (TMI 00686) that its first 510(k) clearance would "seriously undercut those allegations" by Plaintiffs "in the pending products liability litigation against AcroMed."

274. In 1995, Danek submitted a 510(k) notification requesting clearance to market pedicle screws for use in its TSRH system. The claim of substantial equivalence to a pedicle screw device in commercial distribution prior to 1976, which was necessarily required to obtain 510(k) clearance, was based primarily on the Mayock and Wendt affidavits, the former of which was overtly false, and the other, materially misleading.

275. Based on and in reliance on the representations and affidavits contained in Danek's 510(k) submission, on January 20, 1995, the FDA announced its determination that it had cleared pedicle screws pursuant to the Danek 510(k) premarket notification for limited indications. Subsequent clearances were granted to other manufacturers including AcroMed, SNR and Cross based on the Danek clearance.

* * *